PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

11

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
9JI3PC		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/FI00/00914	20.10.2000	21.10.1999
International Patent Classification (IPC) or national classification and IPC7		
G 01 N 33/53, G 01 N 33/543		
Applicant		
OY Medix Biochemica AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14.05.2001	01.02.2002
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88 Telex 17978 PATOREG-S	Authorized officer Yvonne Siösteen/EÖ Telephone No. 08-782 25 00

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FI00/00914

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:
pages 1-21 , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☒ the claims:
pages _____ , as originally filed
pages _____ , as amended (together with any statement) under article 19
pages _____ , filed with the demand
pages 22-24 , filed with the letter of 29.11.2001

☒ the drawings:
pages 1-10 , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☐ the sequence listing part of the description:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims	1-12	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The present invention relates to a test device with a lid-provided pretreatment portion mounted on the same backing support as a test strip and having means for controlled regulation of sample and diluent flow. The test device is useful in field tests and bed-side methods, especially in emergency situations when a rapid result is needed. There is no need for carrying out pretreatment procedures such as coagulation or centrifugation of whole blood samples. The test device has means for regulating the sample and diluent flow. The excess fluid collecting compartment prevents uncontrolled backwash.

Reference is made to the following documents:

A) EP 0806666
B) EP 0323605
C) EP 0582231

A test device for assaying ligands in whole blood without prior separation of erythrocytes and other cells from the blood is disclosed in document A. Figure 1 shows a test device which includes a cell trap covered by a lid (5) having an aperture (4). The device includes a cell trap at the point of entry for test sample into a hydrophilic sample introduction membrane. The trap (1) in fig 1 is disposed in fluid communication with the sample introduction membrane (3) which is in fluid communication with the dye impregnated membrane (15). The trap consists of multiple layers of fibre (see fig3, 6a and 6b). Erythrocytes in an analyte sample applied to the cell trap will pass through one or more layers of overlapped fibers (see column 5, lines 50-58). The device also includes fluid gullys as additional reservoirs for excess liquid

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V

(See fig.5, 40 and 41 and column 9, line 17-25) and a vertical bar (34, not shown) which extends downward from cover 25 to hold dye impregnating membrane 15 in place along slope 33 (see column 9, line 10-16). The excess fluid remains in the gully and is not allowed to be absorbed by the dye impregnating membrane.

Documents B and C also disclose test devices for solid phase assay of an analyte employing capillary flow of reagents and/or sample in the porous solid phase. The devices comprise filtration means which remove particles of a certain size from the test sample.

The claimed device differs from known devices in that it allows the excess fluid compartment to be emptied in an even flow so that all excess fluid is absorbed into the test strip and that negative backlash avoided . This is achieved by including several means (7,8 and 9) for securing and fixing the position of the layer/layers and including a bar which forms an excess fluid collecting compartment (6) behind the pretreatment layers. In this way a controlled regulation of sample and diluent flow is obtained.

Thus, the claimed invention implies an improved effect compared to prior art.
Therefore, claims 1-12 are novel and considered to involve an inventive step.

Claims:

1. A lid-provided backing support for a test device for performing assays without separate pretreatment of the sample, comprising a pretreating system mounted on the backing support (1) and covered and protected by a lid (2) with an aperture (3) in a lid-portion, said pretreatment system having one or more layers (4) horizontally stapled on each other and assembled in a capillary flow connection with a test strip (5), c h a r a c t e r i z e d in that said lid and the lid-portion of said lid-provided backing support is provided with means (7, 8 and 9) of different sizes and heights for securing and fixing the positions of the layers of the pretreatment system, said means comprising taps (7) supporting the pretreatment layers (4), preventing the layers (4) from lying directly on the lid-provided backing support (1) and forcing the sample solution and diluent to pass through the pretreatment layers (4) in predetermined order before entering into the test strip (5), side wall protrusions providing flanking supports (8) preventing the pretreatment layers from moving backwards or in side direction, and bars (9), which can be of different heights and sizes, which fix the pretreatment layers and act as fastening and supporting means for the pretreatment layers (4.1) and (4.2) and the test strip (5), and at least one bar (9.4), which forms a compartment (6) which allows excess sample solution and diluent to be collected behind the pretreatment layers and negative backwash effects to be avoided, and said compartment (6) to be emptied by controlled and even flow by capillary forces of the sample and diluent through each layer in predetermined order and subsequently into and along the test strip (5).

2. The lid-provided backing support according to claim 1, c h a r a c t e r i z e d in that the flanking support preventing the pretreatment layers from moving backwards (8.1) is placed in the rear end of the lid-portion of the

lid-provided backing support (1) and assists in the formation of the compartment (6) for excess liquid.

3. The lid-provided backing support according to claim 1, characterized in that the flanking supports (8.2) preventing the pretreatment layers from moving in side directions simultaneously force the sample solution and diluent to move through the layers in predetermined order and prevent them from passing outside the layers along the backing support.

4. The lid-provided backing support according to claim 1, characterized in that the means for securing and fixing the pretreatment layers comprises at least one toothed bar (9.3), which secures the connection between the pretreatment layer and the conjugate pad (B) of the test strip.

5. The lid-provided backing support according to claim 1, characterized in that the pretreatment system comprises one or more layers (4) providing physical and/or chemical means for pretreating the sample.

6. The lid-provided backing support according to claim 5, characterized in that the physical means for separating and/or removing components from the sample solution are provided by filter layers with variable thickness and size.

7. The lid-provided backing support according to claim 5, characterized in that the physical means for separating and/or removing components from the sample solution comprise one or more filter layers having shaped pores with different diameters on each side of the filter layer.

8. The lid-provided backing support according to claim 1, characterized in that the chemical means for treating the sample solution comprise buffering, ionic

strength regulating, agglutinating, disrupting, extracting, immunocapturing, immunocatalytic, coagulating and/or lytic agents as well as catalyzators, labels, markers, enzymes, substrates and/or reagents.

9. A method for carrying out a rapid bed-side or field test with the lid-provided backing support according to any of claims 1-8, which lid-provided backing support comprises pretreatment layers and a test strip, c h a r a c t e r i - z e d in that it comprises the steps
(a) adding a liquid sample through the aperture (3) in the lid (2) placed on the pretreatment layers of the lid-provided backing support;
(b) adding a diluent, which is capable of redissolving from the pretreatment layers the reagents impregnated therein; mixing the sample with redissolved reagents and driving the sample and reagent mixture through the pretreatment layers, whereby particles are captured and interfering substances are removed in a controlled manner;
(c) collecting the excess liquid in the compartment (6) to enable a controlled and even flow through the pretreatment layers into the test strip (5); and
(d) recording the visible or readable result in the test strip.

10. The use of the lid-provided backing support for a test device according to any of claims 1 to 8 for assessing ferritin from blood.

11. The use of the lid-provided backing support for a test device according to any of claims 1 to 8 for screening the risk of developing iron deficiency anemia.

12. The use of the lid-provided backing support for a test device according to any of claims 1 to 8 for screening presence of environmental contaminants.

PA NT COOPERATION TREAT

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 26 June 2001 (26.06.01)	
International application No. PCT/FI00/00914	**Applicant's or agent's file reference** 9J13PC
International filing date (day/month/year) 20 October 2000 (20.10.00)	**Priority date** (day/month/year) 21 October 1999 (21.10.99)
Applicant SVENS, Eivor, Helena	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

14 May 2001 (14.05.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Charlotte ENGER
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

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(71) Applicant *(for all designated States except US)*: **OY MEDIX BIOCHEMICA AB** [FI/FI]; Asematie 13, FIN-02700 Kauniainen (FI).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **SVENS, Eivor, Helena** [FI/FI]; Parolantie 9 C, FIN-02200 Espoo (FI).

(74) Agent: **BORENIUS & CO OY AB**; Kansakoulukuja 3, FIN-00100 Helsinki (FI).

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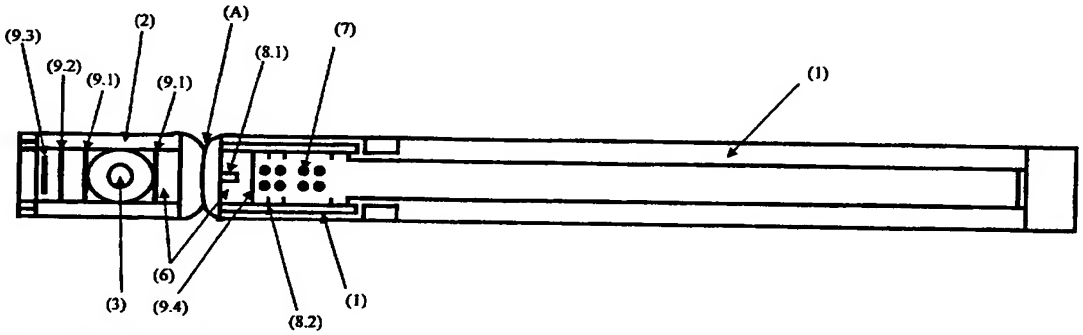
Published:
— *With international search report.*
— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: A TEST STRIP PROVIDED DEVICE WITH A LID-PROVIDED PRETREATMENT PORTION



(57) Abstract: The present invention is related to a test device provided with a pretreatment portion covered by a lid (2) with an aperture (3), which is fastened with hinges (A). The pretreatment portion is mounted on the same backing support (1) as a test strip (not shown). The lid (2) and the lid portion of the backing support is provided with means (7, 8 and 9), which support, secure and fix the position of the pretreatment layers, form a compartment (6) for collecting excess sample and regulate the flow of sample solution and diluent. The test device is useful in field tests and bed-side methods, especially in emergency situations when a rapid result is needed.

WO 01/29558 A1

Claims:

1. A test device for performing assays without separate pretreatment of the sample, c h a r a c t e r i z e d in that the test device is provided with a pretreating system mounted on a backing support (1) and covered and protected by a lid (2) with an aperture (3), said pretreatment system having one or more layers (4) horizontally stapled on each other and assembled in a capillary flow connection with a test strip (5), said lid and the lid-portion of the backing support being provided with means (7, 8 and 9) for securing and fixing the position of the layers in the pretreatment system, said means forming an excess fluid collecting compartment (6), enabling a controlled and even flow by capillary forces of the sample and diluent through each layer in a predetermined order and subsequently into the test strip (5).

2. The test device according to claim 1, c h a r a c t e - r i z e d in that the means for securing and fixing the layers of the pretreatment system comprises taps (7), flanking supports (8) and bars (9) of different heights and sizes.

3. The test device according to claim 2, c h a r a c t e - r i z e d in that the taps (7) supporting the pretreatment layers (4) prevent the layers (4) from lying directly on the backing support (1) and force the sample solution and diluent to pass through the pretreatment layers (4) in predetermined order before entering into the test strip (5).

4. The test device according to claim 2, c h a r a c t e - r i z e d in that it comprises wall protrusions providing flanking supports (8) preventing the pretreatment layers from moving backwards or in side direction.

5. The test device according to claim 4, c h a r a c t e - r i z e d in that the flanking support preventing the

pretreatment layers from moving backwards (8.1) is placed in the rear end of the lid-portion of the backing support (1) and assists in the formation of the compartment (6) for excess liquid.

6. The test device according to claim 4, c h a r a c t e - r i z e d in that the flanking supports (8.2) preventing the pretreatment layers from moving in side directions simultaneously force the sample solution and diluent to move through the layers in predetermined order and prevent them from passing outside the layers along the backing support.

7. The test device according to claim 2, c h a r a c t e - r i z e d in that the means for securing and fixing the pretreatment layers comprises in the lid and lid-portion of the backing support the bars (9), which fix the filtering layers and acts as fastening and supporting means for the pretreatment layers (4.1) and (4.2) and the test strip (5).

8. The test device according to claim 7, c h a r a c t e - r i z e d in that the means for securing and fixing the pretreatment layers comprises in the lid-portion of the backing support at least one bar (9.4), which forms the compartment (6) for collecting excess sample solution and diluent.

9. The test device according to claim 7, c h a r a c t e - r i z e d in that the means for securing and fixing the pretreatment layers comprises at least one toothed bar (9.3), which secures the connection between the pretreatment layer and the conjugate pad (B) of the test strip.

10. The test device according to claim 1, c h a r a c t e - r i z e d in that the pretreatment system comprises one or more layers (4) providing physical and/or chemical means for pretreating the sample.

11. The test device according to claim 1, c h a r a c t e r i z e d in that the physical means for separating and/or removing components from the sample solution are provided by filter layers with variable thickness and size.

12. The test device according to claim 1, c h a r a c t e r i z e d in that the physical means for separating and/or removing components from the sample solution by one or more filter layers having shaped pores with different diameters on each side of the filter layer.

13. The test device according to claim 1, c h a r a c t e r i z e d in that the chemical means for treating the sample solution comprise buffering, ionic strength regulating, agglutinating, disrupting, extracting, immunocapturing, immunocatalytic, coagulating and/or lytic agents as well as catalyzators, labels, markers, enzymes, substrates and/or reagents.

14. A method for carrying out a rapid bed-side or field test without separate pretreatment of the sample, c h a r a c t e r i z e d in that it comprises the steps
(a) adding a liquid sample through the aperture (3) in the lid (2) placed on the backing support (1) of the test device;
(b) adding a diluent, which is capable of redissolving from the pretreatment layers the reagents impregnated therein; mixing the sample with redissolved reagents and driving the sample and reagent mixture through the pretreatment layers, whereby particles are captured and interfering substances are removed in a controlled manner;
(c) collecting the excess liquid in the compartment (6) to enable a controlled and even flow through the pretreatment layers into the test strip (5); and
(d) recording the visible or readable result in the test strip.

15. The use of the test device according to any of claims 1 to 12 for assessing ferritin from blood.

16. The use of the test device according to any of claims 1 to 12 for screening the risk of developing iron deficiency anemia.

17. The use of the test device according to any of claims 1 to 12 for screening presence of environmental contaminants.